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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/351,617 07/12/99 MEHTA

V 15966-518-(C

HM22/0620

IVOR R ELRIFI  
MINTZ LEVIN COHN FERRIS GLOVSKY & POPEO  
ONE FINANCIAL CENTER  
BOSTON MA 02111

EXAMINER

PONNALURI, P

ART UNIT

PAPER NUMBER

1627

DATE MAILED:

14  
06/20/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

# Office Action Summary

Application No.  
09/351,617

Applicant(s)  
Mehta et al

Examiner  
P. Ponnaluri

Art Unit  
1627



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Mar 23, 2001.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 6, 12-20, 23, 24, 26, 27, and 31-34 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 6, 12-20, 23, 24, 26, 27, and 31-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☒ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

1. The amendment B, filed on 3/23/01 has been fully considered and entered into the application.
2. The amendment to the specification page 10, has been entered into the application.
3. New claims 32-34 have been added and claims 1, 6, 13-14, 16-18, 26-27, and 31 have been amended by the amendment B, file don 3/23/01.
4. Claims 1, 6, 12-24, 26-27 and 31-34 are currently pending in this application.
5. Claims 21-22 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected species election. Election was made **without** traverse in Paper No. 9, filed on 8/3/00.
6. This application contains claims 21-22 which are drawn to an invention nonelected with traverse in Paper No. 9. A complete reply to the final rejection must include cancellation of nonelected claims.
7. Claims 1, 6, 12-20, 23-24, 26-27 and 31-34 are currently being examined in this application.
8. The oath or declaration is defective. **A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.**

The oath or declaration is defective because:

It was not executed in accordance with either 37 CFR 1.66 or 1.68.

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The oath and declaration filed on 3/23/01 does not include all the inventors. The new oath/declaration does not include all the inventors.

9. Applicant is invited to notice that boxes 5, 10 and 12 were checked by the draftsman. If applicants renumber the figures, applicant is encouraged to amend the specification so that the description of renumbered figures corresponds to the renumbered figures.

10. In view of applicants amendments to the claims, the 35 U.S.C. 112, second paragraph rejections set forth in the previous office action have been withdrawn.

11. The 35 U.S.C. 103 rejection of claims over WO 94/18317 in view of US Patent 5,610,015 has been withdrawn in view of applicants amendments and arguments.

***Rejections necessitated by the Amendment***

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claim 33 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

The 'clavulanate and sulbactam' claimed in claim 33 has no clear support in the specification and the claims as originally filed. The specification pages 9-13, do not recite these

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ligands as suggested by the applicants in the amendment filed on 3/23/01. The subject matter claimed in claim 33 broadens the scope of the invention as originally disclosed in the specification.

If applicants disagree, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the specification.

### ***Response to Arguments***

14. *The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.*

15. *Claims 1, 6, 12, 17, 19, 20, and 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Licitra et al (Proc. Natl. Acad. Sci. USA., vol. 93, pp. 12817-12821, November 1996) (cited by applicants in the PTO-1449, filed on 12/9/99) set forth in the previous office action mailed on 10/23/00.*

16. *Applicant's arguments filed on 3/23/01, regarding the rejection of claims over Licitra et al, have been fully considered but they are not persuasive.*

*Applicants argue that Licitra does not teach that ligand A forms irreversible (covalent) bond with a predetermined target for which ligand has specificity. Applicants arguments have been considered, however, are not persuasive. Because the reference teaches the three hybrid system "hook-bait-fish" (figure 2), in which the bait has 'A' and 'B' components linked by a linker. The 'hook' consists of a receptor for 'A' component of the 'bait'. The reference teaches*

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*that the ligands 'A' binds to the receptor fused to a DNA binding domain (the 'hook'), and the ligand 'B' binds to the receptor fused to a transcriptional activation domain (the 'fish'). Thus the reference teaches the binding of ligand 'A' to the target (or the receptor). The reference does not recite that the binding of ligand 'A' to the target is "irreversible". In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the reduction of the three-hybrid system to a two hybrid system) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Since the reference ligand 'A' binds to the receptor, and in the absence of teachings by the reference that the ligand 'A' is cleaved from the receptor (or target) for the activation of the reporter gene, the bond between the ligand 'A' and the receptor is a covalent bond. The rejection is maintained for the reasons set forth in the previous office action.*

17. *Claims 1, 6, 12-17, 19-20, 23-24, 26-27 and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,928,868 (Liu et al) (cited by applicants in the PTO-1449, filed on 12/9/99) for the reasons set forth in the previous office action mailed don 10/23/00.*

18. *Applicant's arguments filed on 3/23/01, regarding the rejection of claims over Liu et al, have been fully considered but they are not persuasive.*

*Applicants argue that Liu et al do not teach that ligand A forms irreversible (covalent) bond with a predetermined target for which ligand has specificity. Applicants arguments have*

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*been considered, however, are not persuasive. Because the reference teaches the three hybrid system "hook-bait-fish" (figure 2), in which the bait has 'A' and 'B' components linked by a linker. The 'hook' consists of a receptor for 'A' component of the 'bait'. The reference teaches that the ligands 'A' binds to the receptor fused to a DNA binding domain (the 'hook'), and the ligand 'B' binds to the receptor fused to a transcriptional activation domain (the 'fish'). Thus the reference teaches the binding of ligand 'A' to the target (or the receptor). The reference does not recite that the binding of ligand 'A' to the target is "irreversible".*

*In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the reduction of the three-hybrid system to a two hybrid system) are not recited in the rejected claim(s).*

*Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Since the reference ligand 'A' binds to the receptor, and in the absence of teachings by the reference that the ligand 'A' is cleaved from the receptor (or target) for the activation of the reporter gene, the bond between the ligand 'A' and the receptor is a covalent bond. The rejection is maintained for the reasons set forth in the previous office action.*

19. *Claims 1, 6, 12, 17, 19, 20, 23-24 and 31, and new claims 32, 34, are rejected under 35 U.S.C. 103(a) as being unpatentable over Licitra et al (Proc. Natl. Acad. Sci. USA, vol. 93, pp 12817-12821, November 1996) (cited by applicants in the PTO-1449, filed on 12/9/99) for the reasons set forth in the previous office action mailed on 10/23/00.*

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*Applicant's arguments filed on 3/23/01, regarding the rejection of claims over Licitra et al,*

*have been fully considered but they are not persuasive. Applicants argue that Licitra does not disclose, motivate or suggest the providing of a preactivated ligand A, and reagents for forming a hybrid molecule with at least one type of ligand B, wherein ligand A has a specificity for a predetermined target and forms an irreversible bond. Applicants arguments are not persuasive, because Licitra et al teach the three hybrid system "hook-bait-fish" (figure 2), in which the bait has 'A' and 'B' components linked by a linker. The 'hook' consists of a receptor for 'A' component of the 'bait'. The reference teaches that the ligands 'A' binds to the receptor fused to a DNA binding domain (the 'hook'), and the ligand 'B' binds to the receptor fused to a transcriptional activation domain (the 'fish'). Thus the reference teaches the binding of ligand 'A' to the target (or the receptor) and nowhere in the reference it teaches that the ligand "A" need to be activated before binding to the target, that means that the ligand 'A' is preactivated. And the reference teaches that dexamethasone binds to glucocorticoid receptor (thus, it is known that the ligand 'A' binds to a predetermined target). The reference does not recite that the binding of ligand 'A' to the target is "irreversible". Thus, ligand 'A' binds to the receptor is irreversible. The rejections have been maintained for the reasons of the record.*

*The new claims 32 and 34 have been included in this rejection since the reference teaches that the system is useful for any type of ligand or any type of synthetic organic compound, and the reference teaches the advantages of the method in drug discovery. Thus, it*



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*would have been obvious to one skilled in the art use other types of ligands in the method taught by Licitra et al*

20. No claims are allowed.

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Ponnaluri whose telephone number is (703) 305-3884. The examiner can normally be reached on Monday to Thursday from 6.30 AM to 4.00 PM. The examiner can also be reached on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venakt, Ph.D., can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

P. Ponnaluri  
Art Unit 1627  
15 June 2001

  
**PADMASHRI PONNALURI**  
**PRIMARY EXAMINER**